

Medicare Participating Heart Bypass Center Demonstration: Appropriateness Study - Model for the Use of CABG and PTCA

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1.0 INTRODUCTION

Practice guidelines are being advocated for their potential to improve both the appropriateness and outcomes of health care. Interest in practice guidelines stem from widespread variations in practice patterns in the absence of corresponding differences in medical outcomes, studies that suggest that between 15 and 30 percent of selected procedures are performed for inappropriate reasons (Leape 1990), and the continued upward spiral in health care costs.

This report describes the development of an appropriateness model for the use of CABG and PTCA in patients with coronary artery disease in the context of the Medicare Participating Heart Bypass Center demonstration being conducted by the Health Care Financing Administration's (HCFA) Office of Research and Demonstrations. This project is testing the use of a negotiated package price for hospital and physician services rendered during an episode of care involving CABG surgery. The appropriateness model will be used to examine patient selection for CABG and PTCA in these centers. PTCA utilization will be evaluated, in addition to CABG, because of the overlap of clinical indications for these two procedures and the possible influence of the package price payment mechanism on patient selection.

The development of this model involved three essential steps. First, literature pertaining to the effectiveness of CABG and PTCA was systematically reviewed. Second, based on the literature review, a matrix of potential clinical indications was developed that included patient characteristics that were felt to influence the benefits and risks of these procedures. Third, an expert panel rated the appropriateness of specific indications during a two-stage modified delphi process similar to that developed by the RAND Corporation in its Health Services Utilization Study (Chassin et al 1986).

Our primary goal has been to develop appropriateness criteria that are:

- (1) inclusive of the common manifestations of coronary artery disease;
- (2) reflect the importance of the characteristics of the individual patient in determining the balance between the benefits and risks of the procedure; and
- (3) indicate whether use of the procedure is appropriate, inappropriate, or

equivocal in each type of patient and, if appropriate, the degree of appropriateness. Use of this model will permit assessment of utilization of CABG and PTCA in the Medicare Participating Bypass Centers in terms of total expected net benefits (the excess of benefits over risks) as well as the proportion of cases that are deemed "appropriate."

A second purpose of the study is to examine the stability of this appropriateness rating methodology when it is applied by two independent panels of experts. To this end, we will compare our ratings to those of a similar panel convened by the RAND Corporation. Areas of agreement between the two panels will increase confidence in the conclusions reached, while differences of opinion will indicate areas of uncertainty that require further evaluation.

2.0 METHODS

2.1 Literature Review

Literature assessing the efficacy (effectiveness), risks, complications, indications, costs, and utilization of CABG and PTCA published prior to mid-1990 was systematically reviewed. Emphasis in these reviews was placed on information from controlled clinical trials and prospective cohort studies because of their greater internal validity. Two literature reviews were produced by The RAND Corporation with assistance from one of the authors of this report (WBS).

"Coronary Artery Bypass Graft Surgery: A Review of the Literature Regarding Efficacy and Risks." Authors: Lucian L. Leape, M.D., Lee H. Hilborne, M.D. M.P.H., William B. Stason, M.D., M.S., Caren J. Kamberg, M.S.P.H., and Robert H. Brook, M.D., Sc.D.

"Percutaneous Transluminal Coronary Angioplasty: A Review of the Literature Regarding Efficacy and Risks." Authors: Lee. H. Hilborne, M.D., M.P.H., Lucian L. Leape, M.D., Caren J. Kamberg, M.S.P.H., Robert H. Brook, M.D., Sc.D.

A third review, entitled "Indications for Coronary Artery Bypass Grafting in the HCFA Coronary Artery Surgery Demonstration," written by Lewin/ICF, targetted selected areas of progress in the technologies and clinical applications of CABG and PTCA were felt to be particularly germane to the Demonstration.

The purpose of these literature reviews (Appendices A,B, and C) was to provide up-to-date information for members of our Technical Advisory Panel (TAP) prior to the time they performed their initial ratings of clinical indications.

2.2 Matrix of Clinical Indications

An initial matrix of the clinical indications was developed from information in the published literature. This matrix was then modified by a consensus panel convened by the RAND Corporation in November, 1990. HCFA's Technical Advisory Panel (TAP) performed its first set of ratings on this modified matrix:

Indications were grouped according to clinical subpopulations of patients with coronary artery disease into eight chapters:

1. Chronic Stable Angina.
2. Unstable Angina.
3. Acute Myocardial Infarction (less than 6 hours).
4. Post Myocardial Infarction (6 hours to 21 days).
5. Asymptomatic Patients with Coronary Artery Disease.
6. Near Sudden Cardiac Death.
7. Coronary Artery Disease in Patients Requiring Valve Surgery.
8. Palliative PTCA in Patients Who Are Not Candidates for CABG.

These clinical subpopulations were further classified by patient characteristics that are important determinants of benefits or risks of CABG

or PTCA. These characteristics varied by population subgroup but included:

1. Severity of angina (mild or moderate (class I or II) or severe (class III or IV));
2. anatomic location and extent of coronary artery disease;
3. ejection fraction ($>35\%$, $15-35\%$, $<15\%$);
4. maximal or less than maximal medical therapy;
5. exercise tolerance test results (strongly positive or negative or weakly positive);
6. presence of cardiogenic shock;
7. transmural or non-transmural myocardial infarction;
8. use of thrombolytic agents; and
9. clinical risk due to non-cardiac comorbidities.

2.3 Definitions of Variables

Uniform definitions of key variables provide an essential foundation both for obtaining valid ratings of clinical indications by panelists and to subsequent appropriateness reviews aimed at evaluating the appropriateness of care in an institution. To this end, the following definitions were agreed upon.

Unstable Angina: Chest pain thought to be due to myocardial ischemia, requiring hospitalization because of difficulty in control or concern about the possibility of myocardial infarction; includes 1) recent increase in the intensity, frequency, or duration of chronic angina, 2) the development of angina at rest, or 3) new onset of severe chest pain ("acute coronary insufficiency").

Asymptomatic Coronary Artery Disease: A patient with significant coronary artery disease who has no history of angina. Includes patients screened for risk factors, high risk occupations, and prior myocardial infarction.

Angina Class (Canadian Cardiovascular Society Classification):

- Class I = Angina on strenuous exertion.
- Class II = Angina on walking or climbing stairs rapidly.
- Class III = Angina on walking one or two level blocks.
- Class IV = Angina on any physical activity; (also include for this patient: angina at rest).

Significant Coronary Artery Disease:

Left main disease: 50 percent or greater reduction in the luminal diameter of the left main coronary artery on angiography.

Three-vessel disease: 50 percent or greater reduction in the luminal diameter of all three major coronary arteries on angiography, with at least one lesion 70 percent or greater.

Two-vessel disease: 50 percent or greater reduction in the luminal diameter of two major coronary arteries, with at least one lesion 70 percent or greater.

One-vessel disease: 70 percent or greater reduction in the luminal diameter of one major coronary artery (not left main).

Maximum Medical Therapy: The patient has received drugs from at least two of the three major categories (nitrates, beta-blockers, and calcium antagonists) OR the patient has received one class of medication but there is a note in the chart that the patient is unable to tolerate the others.

Positive Stress ECG:

Very Positive Stress ECG: (a) During the first three minutes of the test (or onset at heart rate less than 120 beats/minute off beta-blockers, or less than 6.5 METS) the patient develops: (1) 1mm or more of horizontal or downsloping ST segment depression that is present 80msec after the J-point or (2) the occurrence of typical angina; OR (b) a decrease in systolic blood pressure of 20mm mercury or more; OR (c) more than 2mm of horizontal or downsloping ST depression at any time, OR (d) persistence of ST depression for greater than six minutes post-exercise.

Positive Stress ECG: After the first three minutes of the test the patient develops: (1) 1mm or more of horizontal or downsloping ST segment depression that is present 80msec after the J-point or (2) typical angina occurs.

Indeterminate or Negative Stress ECG: Absence of any of the above findings.

Levels of risk (Modified Parsonnet Score): The Parsonnet Score (Parsonnet 1989) was chosen to classify patients by risk. This model includes the left ventricular ejection fraction and therefore, results in some redundancy with respect to the clinical indications to be rated. Nonetheless, this risk score provides a useful way to summarize the effects of comorbidities. Modifications to the Parsonnet Score were made by the panel to account for important comorbidities not included in the model, including:

1. COPD requiring continuous medications - +4 points
2. Peripheral vascular disease with claudication - +3
3. Symptomatic carotid disease - +4

Categories of Risk:

Low Risk: Patient has no or few risk factors. Operative mortality risk is not significantly increased. (Parsonnet score 0-8.)

Moderate Risk: Expected operative mortality is 2-4 times that of low-risk patients because of significant comorbidity, advanced age, re-operation, or associated non-coronary heart disease. (Parsonnet score 9-18.)

High Risk: Expected operative mortality is more than four times that of low risk patients because of significant comorbidity, advanced age, associated non-coronary heart disease. (Parsonnet score greater than 18.)

General Contra-Indications to CABG: Although these contraindications apply to PTCA as well, PTCA may be considered for palliative relief of severe pain.

1. Terminal illness, such as cancer, AIDS, severe COPD, hepatic failure, where a reasonable prognosis is six months or less.
2. Advanced dementia.
3. Severe impairment in ability to perform basic activities of daily living because of non-cardiac disease (Katz score of 3/6 or below).

Candidate for PTCA: A patient with significant coronary artery disease in whom the characteristics of the lesions are such that there is a reasonable probability that dilatation can be accomplished without unusual risk.

Candidate for CABG: A patient with significant coronary artery disease in whom the characteristics of the lesions are such that there is a reasonable probability that coronary artery bypass grafting can be accomplished without unusual risk.

2.4 Selection of the Technical Advisory Panel

The Technical Advisory Panel was selected from a national list of experts in cardiovascular surgery, invasive cardiology, and non-invasive cardiology or general internal medicine. This list was compiled from recommendations made by relevant specialty societies, identification of authors of key articles, and recommendations of experts known to the investigators. Our plan was to convene a panel of six to nine members with balanced representation of at least two physicians from each discipline. Initially, nine panelists were selected but, subsequently, one member had to resign because of illness and another withdrew because of a scheduling conflict. A representative of a payor organization was added at the request of HCFA's Office of Research and Demonstrations to provide the payor's perspective.

The final panel included the following members:

Cardiac Surgery

William Gay, M.D.
Department of Surgery
University of Utah School of Medicine

Frederick L. Grover, M.D.
University of Texas Health Science Center
Division of Cardiothoracic Surgery

Daniel Ulyot, M.D.
Private Practice
Burlingame, CA 94010

Invasive Cardiologists

Stuart Seides, M.D.
Cardiology Associates
Washington, DC 20010

Richard Stack, M.D.
Director, Interventional Programs
Duke University Medical Center

Cardiologists/Referring Physicians

Bernard J. Gersh - B. Chir. D. Phil.
Professor of Medicine
Mayo Medical School

Alvin Blaustein, M.D.
Cardiology Section
V.A. Medical Center
Cincinnati, OH 45220

Payor

W. Knox Fitzpatrick, M.D.
Vice President for Medical Affairs
Blue Cross/Blue Shield of Utah
Salt Lake City, UT 84109

2.5 Initial Appropriateness Ratings

The literature reviews, instructions for performing the appropriateness ratings (Appendix D), and initial rating sheets (Appendix E) were sent to the panelists three weeks before the scheduled TAP meeting. Rating sheets listed all indications and provided space to rate each indication on a 1 to 9 scale for each treatment comparison: CABG versus medical therapy in the patient who is not a candidate for medical therapy; CABG versus PTCA in a patient suitable for either procedure; and PTCA versus medical therapy. Each indication/treatment combination was rated for three levels of patient risk from comorbidities (see Definitions). Figure 1 provides a sample rating sheet.

Instructions asked the panelists to rate the appropriateness of each indication using their best clinical judgment for the "average patient" with the indication treated by the "average physician" who performs the procedure in 1991. Appropriate was defined to mean "that the expected health benefits (i.e., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceed the expected health risks (i.e.,

FIGURE 1 - SAMPLE RATING SHEET

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Chapter 3

CHRONIC STABLE ANGINA

[illegible]

mortality, morbidity, anxiety of anticipating the procedure, pain produced by the procedure, time lost from work) by a sufficiently wide margin that the procedure is worth doing and is superior to the alternative treatment." A rating of 9 indicates that benefits greatly exceed risks; a rating of 1 indicates that risks greatly exceed benefits; and a rating of 5 indicates either that benefits and risks are about equal or the degree of uncertainty about benefits and risks is great.

Panelists were asked to rate all indications even if they appeared to be unacceptable practices. Furthermore, they were encouraged to add or modify indications if they wished (none did).

A total of 2,984 indications were rated during this first round. Self-reported times required to complete the ratings ranged from four to eight hours.

2.6 Meeting of the Technical Advisory Panel

The TAP met in Washington, D.C. for two days during January, 1991. First, the literature reviews were discussed. Comments focused primarily on studies published since the literature reviews were performed, studies in progress, and residual areas of uncertainty. The most telling points that were made related to current controversy over the relative merits of CABG and PTCA in patients with two or three vessel disease and stable or unstable angina and the use of these procedures following myocardial infarction. Several controlled clinical trials are underway to examine these issues. Indications for these procedures may well change in response to the results of these studies when they are completed in the next 2-4 years. Another area of uncertainty is that of the treatment of the "sudden death" patient. Effectiveness studies are sparse, and further information is needed to clarify the appropriate roles of CABG and PTCA, as well as those of electrophysiologic studies and use of the automatic implantable cardiac defibrillator (AICD). The most important message, perhaps; is that invasive treatment of coronary artery disease is a rapidly evolving field. Progress will need to be reviewed and indications updated in 2-3 years.

Discussion then proceeded chapter-by-chapter, starting with Chronic Stable Angina. Results of first-round ratings of indications were distributed to the panelists. Each panelist received his or her own ratings and the distribution of ratings for the entire panel. Figure 2 presents a sample rating print-out. The numbers above the 1-to-9 rating line show how many panelists assigned each rating. The caret below the line shows the rating assigned by a particular panelist. For example, the panelist whose report is shown rated the first indication "1," the second indication "9," and the third indication "6." For the group as a whole, four panelists rated the first indication "1" and four panelists rated it "2." This procedure preserved the confidentiality of individual panelist's ratings while allowing each panelist to see his own rating in comparison to the distribution of ratings for the whole panel.

The indications for each chapter were discussed and changes were made to reflect decisions made by the panel. The panelists then independently re-rated the revised indications.

The following changes were made to the initial set of indications:

ALL CHAPTERS:

Ejection fraction categories were changed from: >35 %, 15-35%, <15% to, >50%, 25-50%, <25%.

Chapter 1 - Chronic Stable Angina:

No other changes.

Chapter 2 - Unstable Angina:

- (1) The distinction between maximal and less than maximal medical therapy was eliminated for patients with continuing symptoms; and
- (2) "No Symptoms on Maximal Medical Therapy" was changed to "Stabilized on Medical Therapy."

Chapter 3 - Acute Myocardial Infarction:

- (1) Under "Evolving Myocardial Infarction (first six hours), "Continuing Pain" was changed to "Continuing Pain or Total Occlusion."
- (2) The use or non-use of thrombolysis was added as a patient characteristic.

FIGURE 2

SAMPLE OF FORM USED TO SUMMARIZE INITIAL APPROPRIATENESS RATINGS FOR PANELISTS

Appropriateness Scale									
1	2	3	4	5	6	7	8	9	
1 = extremely inappropriate									
5 = equivocal (neither clearly appropriate nor clearly inappropriate)									
9 = extremely appropriate									

	Rating of Appropriateness (Circle One)
I. Chronic Stable Angina	
A. CABS is indicated despite the presence of strong contraindications	4 1 1 2 3 4 5 6 7 8 9 ^
B. CABS is indicated in patients (without strong contraindications) with left main disease, and	
1. Ejection fraction 20% or greater	1 2 3 4 5 6 7 8 9 1 7 ^
2. Ejection fraction under 20%	1 2 2 1 2 1 2 3 4 5 6 7 8 9 ^
C. CABS is indicated in patients (without strong contraindications) with three-vessel disease, and	
1. Class I or II angina on no or less than maximal medical therapy, and	
a. Ejection fraction 50% or greater	2 1 1 3 1 1 2 3 4 5 6 7 8 9 ^
aa. Ejection fraction 20-49%	3 3 2 1 2 3 4 5 6 7 8 9 ^
b. Ejection fraction under 20%	4 2 1 1 1 2 3 4 5 6 7 8 9 ^

Chapter 4 - Post Myocardial Infarction:

The distinction between transmural (Q-wave) and subendocardial (non-Q-wave) infarction was dropped in patients who are asymptomatic following their infarctions.

Chapter 5 - Asymptomatic Patients with Coronary Artery Disease:

No changes.

Chapter 6 - Near Sudden Death:

This population subgroup generated considerable controversy. After a prolonged discussion, the decision was made to eliminate distinctions based on anatomy, ejection fraction, presence of angina, and exercise stress test positivity. A single indication remained that described a patient "without a Q-wave infarction, with any level of ischemia, any anatomy, and any ejection fraction."

Chapter 7 - Coronary Revascularization with Valve Surgery:

No changes.

Chapter 8 - Sufficient Comorbidities to Preclude CABG Even After PTCA Failure:

No changes.

Following these changes, a total of 828 indications remained, each of which was rated for three levels of risk from comorbidities for a total of 2484 ratings.

2.7 Analysis of Appropriateness Ratings

Methods developed by the RAND Corporation were used to analyze ratings (RAND, 1986). For each indication, the median was used to measure the central tendency of panelists' ratings and the mean absolute distance from the median to measure the degree of dispersion.

The 1 to 9 rating scale is an ordinal scale that ranks the excess of benefit over risk for the comparison of alternative treatments in question. A 9 is a stronger expression of net benefit (or appropriateness) than an 8, and so on. The scale is not a continuous one, however, and intervals between points on the scale are not necessarily equal. Nonetheless, a two-point difference on the scale almost certainly represents a bigger difference in net benefits than a one-point difference.

The degree of agreement among panelists is a measure of the degree of confidence we can place in median ratings. Agreement (A) is defined as having all ratings within a three point spread after the lowest and highest scores have been eliminated. Disagreement (D) is defined by having at least one rating fall between 1 and 3 and one rating fall between 7 and 9 after the highest and lowest scores have been eliminated. Intermediate (I) levels of agreement include all other degrees of dispersion.

3.0 RESULTS OF APPROPRIATENESS RATINGS

Table 1 compares summaries of initial and final ratings. Figures for initial ratings are for all three treatment combinations together, while final ratings are specific to individual treatment comparisons. The most striking results are the decreases observed in the degrees of dispersion: mean absolute deviations decrease from 1.61 in the initial ratings to 1.19 to 1.29 for different treatment comparisons in the final ratings. At the same time, the proportion of indications for which there was "Agreement" among panelists increased from 22.6% to 37.2% - 38.5%.

Table 2 examines chapter-by-chapter levels of agreement and disagreement for the final ratings. The highest levels of agreement occurred for Chronic Stable Angina and Unstable Angina, and least agreement occurred for the treatment of acute myocardial infarction. These findings are consistent with the conclusions, or lack thereof, in published literature. Greater consensus on the appropriate treatment of AMI is very likely to result from studies currently in progress. Interestingly, agreement was high and disagreement low for treatment of the asymptomatic patient with coronary artery disease despite a relative paucity of literature on this population. By definition, procedures are done in these patients to prolong life and preserve myocardium rather than relieve symptoms. To date, convincing evidence on the ability of CABG to prolong life is available only for patients with LMD and 3VD, and these studies predominantly involved symptomatic patients.

Tables 3 through 9 summarize final ratings chapter-by chapter. These tables condense and simplify detailed ratings provided in Appendix E.

TABLE 1

SUMMARY OF INITIAL AND FINAL RATINGS FOR CABG AND PTCA INDICATIONS

	<u>INITIAL RATINGS</u>	<u>FINAL RATINGS</u>		
		<u>CABG Vs. Medical</u>	<u>CABG Vs. PTCA</u>	<u>PTCA Vs. Medical</u>
Number of Indications	2984	828	828	828
Mean of Medians	4.86	6.33	4.33	6.67
Mean of Absolute Deviations From Medians	1.61	1.29	1.19	1.19
Percent Agreement	22.6%	37.2%	37.8%	38.5%
Percent Disagreement	27.1%	17.3%	14.0%	13.6%

TABLE 2

FINAL RATINGS: PROPORTIONS OF AGREEMENT AND DISAGREEMENT AMONG PANELISTS ON INDICATIONS FOR CABG AND PTCA

<u>CHAPTER</u>	<u>CABG VS. MEDICAL</u>	<u>CABG VS. PTCA</u>	<u>PTCA VS. MEDICAL</u>
1 - Chronic Stable Angina			
Percent Agreement	41.9%	41.6%	42.6%
Percent Disagreement	22.5%	12.0%	17.9%
2 - Unstable Angina			
Percent Agreement	42.4%	45.8%	37.5%
Percent Disagreement	13.9%	11.1%	14.6%
3 - Acute Myocardial Infarction			
Percent Agreement	21.9%	26.0%	15.4%
Percent Disagreement	20.3%	19.5%	3.3%
4 - Post Myocardial Infarction			
Percent Agreement	32.7%	30.2%	47.5%
Percent Disagreement	11.1%	19.8%	17.3%
5 - Asymptomatic Patient with Coronary Artery Disease			
Percent Agreement	38.9%	43.1%	38.9%
Percent Disagreement	9.7%	5.6%	2.8%
6 - Near Sudden Death			
Percent Agreement	100%	0%	100%
Percent Disagreement	0%	33.3%	0%

TABLE 3

CHRONIC STABLE ANGINA¹ - LOW OR NORMAL RISK FROM COMORBIDITIES

	CABG VS. MEDICAL RX		CABG VS. PTCA		PTCA VS. MEDICAL RX	
	Anginal Level		Anginal Level		Anginal Level	
	Severe	Mild-Moderate	Severe	Mild-Moderate	Severe	Mild-Moderate
<u>Left Main Disease²</u>						
Maximal R	9.0A	9.0A	9.0A	9.0A	4.5I	3.5I
Submaximal R	9.0A	9.0A	9.0A	9.0A	3.5D	2.5I
<u>Three Vessel Disease³</u>						
Maximal R	9.0A	9.0A	8.0A	6.0-7.5I,A	7.5-8.0A	8.0A,I
Submaximal R	9.0A	9.0A	7.0-8.0A	6.0-7.0A,I	8.0A,I	6.5-7.0A,I
<u>Two Vessel Disease with Proximal LAD Involvement⁴</u>						
Maximal R						
ETT ++	8.5-9.0A	8.0-8.5I,A	7.0-8.0I	5.5-7.0I,A	8.0-9.0A	8.0A,I
ETT +	8.0-9.0A	6.5-7.5I,A	5.0-7.0I	6.5-8.0I	8.0A	6.5-8.0I
Submaximal R						
ETT ++	8.0A	7.5-8.0A,I	6.5-8.0A,D	6.0-7.0A,I,D	8.0A	7.5A,I
ETT +	7.0-7.5I	5.5-6.5I	5.0-5.5D,I	4.5-5.0D,I	7.0-7.5I,A	6.5-7.0A,I
<u>Two Vessel Disease Without LAD Involvement⁴</u>						
Maximal R						
ETT++	8.5-9.0A	7.0-8.0I,D	5.0-6.0I,D	4.5-5.5I	8.0A	7.0-7.5I
ETT+	8.0A,I	5.5-6.0I,D	4.5-5.0I,A	3.0-4.0I,A	8.0A	6.0-6.5I
Submaximal R						
ETT++	7.0I	7.0-7.5A,I	5.0-5.5I,D	3.0-4.0I	7.5-8.0A	7.0-8.0I
ETT+	5.5-6.5I	4.0-5.0D	4.5D	3.0I	5.0-5.5I	5.5I
<u>Single Vessel Disease With LAD Involvement⁵</u>						
Maximal R						
ETT++	8.0A	8.0A,I	5.0-6.5D	3.0-4.0D	8.0-8.5A	8.0A
ETT+	---	5.5-6.5D	---	3.0I	---	6.5-7.0I,A
Submaximal R						
ETT++	7.0-8.0A,D	---	4.0-6.0I,D	---	7.0-7.5A	---
ETT+	---	7.5-8.0A,I	---	2.0-5.0D,I	---	8.0A,I
ETT+	---	3.5-6.0D	---	2.0I	---	5.5-6.0I,D
<u>Single Vessel Disease Without LAD Involvement⁵</u>						
Maximal R						
ETT++	8.0A	---	1.5-3.0I,A	---	8.0A	---
ETT+	---	7.0-7.5I,A,D	---	2.5A	---	7.5-8.0A
ETT+	---	3.0-4.0D	---	1.5-2.0A	---	6.0-6.5D
Submaximal R						
ETT++	5.0-6.0I,D	---	1.5-2.5I	---	7.0I	---
ETT+	---	4.0-7.5D,I	---	1.5-2.5A	---	7.5I
ETT+	---	2.0-2.5D	---	1.0A	---	4.0-5.0D

1. Ranges of scores within categories indicate variations with EF. The letters A, I, and D indicate agreement, disagreement or intermediate results, respectively, as defined in the methods. The first listed of two letters indicates the level of agreement for two of the three ejection fraction levels.
2. Scores are not affected by EF but are about one point lower for CABG in the very high risk group.
3. Scores vary by EF and, where a range is shown, are higher where the EF is 25 to 50 percent. Scores are more sensitive to risk level than for LAD and decrease about two points between the lowest and highest risk stratum.
4. For two vessel disease, both scores and levels of agreement are higher for the 25 to 50 percent EF range. CABG scores fall with increases in risk level and are 2 to 3 points lower in the very high risk group, especially if the EF is <25% and/or the LAD is not involved. PTCA scores are affected less by risk level.
5. The same trends are observed with EF, risk level, and LAD involvement for single vessel disease for two vessel disease.

TABLE 4

UNSTABLE ANGINA - LOW OR NORMAL RISK FROM COMORBIDITIES

	CABG VS. MEDICAL RX		CABG VS. PTCA		PTCA VS. MEDICAL RX	
	Symptoms Persist	No Symptoms on Medical R	Symptoms Persist	No Symptoms on Medical R	Symptoms Persist	No Symptoms on Medical R
<u>Left Main Disease¹</u>	9.0A	9.0A	9.0A	8.5-9.0A	6.5D	3.5D
<u>Three Vessel Disease²</u>	9.0I	8.5-9.0I, A	7.5-8.5I	6.5-8.0I	8.5-9.0A, I	8.0-8.5I, A
<u>Two Vessel Disease With LAD Involvement³</u>						
	9.0A	---	7.0A, D	---	8.5A	---
ETT++	---	8.5-9.0A, I	---	5.0-6.0A, I, D	---	8.5-9.0A, I
ETT±	---	8.0A, I	---	5.0-6.0A, D	---	8.0I, A
<u>Two Vessel Disease Without LAD⁴</u>						
	9.0A	---	5.0A, D	---	8.0-8.5A	---
ETT++	---	8.0I	---	4.0A	---	8.0I, A
ETT±	---	5.5I, D	---	3.0-3.5A	---	5.5-6.0I
<u>Single Vessel Disease With LAD Involvement⁵</u>						
	8.5-9.0A	---	5.0A, I, D	---	9.0A	---
ETT++	---	7.5-8.0A, I	---	4.5-5.5A, D	---	8.0-8.5A, I
ETT±	---	5.0-7.0I	---	4.0-5.0I	---	7.0I
<u>Single Vessel Disease Without LAD Involvement⁶</u>						
	7.5-8.0A, I	---	1.5-3.0I	---	8.0-8.5A	---
ETT++	---	5.5-7.0A, I, D	---	2.0-2.5A	---	8.0A
ETT±	---	2.0-3.0I, D	---	2.0A	---	5.0D, A

Notes:

1. CABG scores are not affected by EF but are about one point lower in the very high comorbidity risk group.
2. In patients with no symptoms on medical therapy, CABG scores are 2-3 points lower in the very high comorbidity risk group. Where a range is given, scores are lower if the EF <25%.
3. Disagreement is most evident in patients with EFs <25%. CABG scores are two or more points lower in the very high risk group. PTCA becomes the preferred procedure in the very high risk group if EF <25% and also in patients with a negative ETT and no symptoms if the EF is >50%. PTCA scores are affected much less by risk level than are CABG scores. The disagreement (D) occurs in the case of EF <25%.
4. Results are similar to those for two vessel disease with LAD involvement except that PTCA is preferred at all EFs in the very high comorbidity risk group.
5. PTCA is preferred over CABG in the very high comorbidity risk group regardless of EF. In other risk strata, the choice between PTCA and CABG is equivocal.
6. In the absence of LAD involvement, PTCA is uniformly preferred over CABG in all risk strata.

TABLE 5

ACUTE MYOCARDIAL INFARCTION (FIRST SIX HOURS) - LOW OR NORMAL RISK FROM COMORBIDITIES

	CABG VS. MEDICAL RX	CABG VS. PTCA	PTCA VS. MEDICAL RX
<u>Cardiogenic Shock¹</u>			
Left Main Disease	8.0A	7.5A	7.5I
Three Vessel Disease	8.0A	6.5I	8.0A
Two Vessel Disease	7.5I	4.0I	8.0A
Single Vessel Disease	7.5I	3.0I	8.0A
<u>Evolving Asymptomatic AMI</u>	2.5I	1.5A	5.0D
<u>Evolving AMI With Continuing Pain</u>			
Left Main Disease ²			
No Thrombolysis	8.5A	7.5-8.0A	5.0-6.0I
Thrombolysis	8.0A	7.0-8.0I	5.0-7.0I
Three Vessel Disease ³			
No Thrombolysis	8.0-8.5A, I	5.0-6.5D	7.0-8.5I, A
Thrombolysis	7.0I	3.5-5.0D, I	8.0-9.0I
Two Vessel Disease			
With LAD Involvement ³			
No Thrombolysis	7.5-8.5A, I	4.0-6.0D	7.0-9.0I
Thrombolysis	7.0-7.5I	3.5-5.0D, I	6.0-9.0I
Two Vessel Disease			
Without LAD Involvement ³			
No Thrombolysis	5.5-6.0I	2.5-4.0I	7.0-8.0I
Thrombolysis	5.0-5.5I	1.5-3.0I	6.0-8.0I
Single Vessel Disease			
With LAD Involvement ³			
No Thrombolysis	7.5-8.5A, I	2.5-4.0D	9.0I
Thrombolysis	6.5-7.5I	2.5-4.0D	8.5I
Single Vessel Disease			
Without LAD Involvement ³			
No Thrombolysis	4.0-5.5D	2.0-2.5I, A	8.0I
Thrombolysis	4.0D	2.0-2.5I, A	8.0I

Notes:

1. CABG scores are about 2 points lower in the very high comorbidity risk group.
2. CABG scores are only one point lower in the very high comorbidity risk group. Scores are lower if EF < 25%.
3. CABG scores are 2+ points lower in the very high comorbidity risk group. Considerable disagreement was expressed for the choice between CABG and PTCA in all risk groups. Scores for both CABG and PTCA are lower if EF < 25%.

TABLE 6

POST MYOCARDIAL INFARCTION (WITHIN 21 DAYS) - LOW OR NORMAL RISK FROM COMORBIDITIES

	<u>CABG VS. MEDICAL RX</u>	<u>CABG VS. PTCA</u>	<u>PTCA VS. MEDICAL RX</u>
<u>Left Main Disease¹</u>			
Continuing Pain	9.0I,A	9.0A,I	5.0A
No Symptoms - ETT++	9.0A,I	9.0A,I	5.0A
No Symptoms - ETT±	7.5-8.5A,I	7.5-8.5A,I	5.0A
<u>Three Vessel Disease¹</u>			
Continuing Pain	8.5-9.0A,I	6.5-7.5A,D	8.0A,I
No Symptoms - ETT++	8.0-8.5A,I	6.0-7.5A,D	7.0-7.5A,I
No Symptoms - ETT±	6.0-7.0I	5.0-6.0A,I	5.5-7.0A,I
<u>Two Vessel Disease</u>			
<u>With LAD Involvement¹</u>			
Continuing Pain	8.0-9.0A,I	6.5-7.0D	8.5-9.0A
No Symptoms - ETT++	7.5-8.0A,I	5.5-7.0D	7.5-8.0A
No Symptoms - ETT±	5.5-6.5I	4.0-5.0A,I,D	6.0-7.0I
<u>Two Vessel Disease</u>			
<u>Without LAD Involvement¹</u>			
Continuing Pain	8.0A	3.5-5.0D,I	7.5-8.0A
No Symptoms - ETT++	7.0-7.5A,I	2.5-5.0I	6.5-7.0I
No Symptoms - ETT±	4.0-5.0I,D	3.5-4.5I	4.0-5.0D,I
<u>Single Vessel Disease</u>			
<u>With LAD Involvement¹</u>			
Continuing Pain	8.0I,A	5.0-5.5D,I	8.5-9.0A
No Symptoms - ETT++	6.5-7.5A,I	3.5-5.0D,I	7.5-8.0A,I
No Symptoms - ETT±	4.0-5.0D	2.5I	5.5-7.0D
<u>Single Vessel Disease</u>			
<u>With LAD Involvement¹</u>			
Continuing Pain	6.5-7.0A	2.5-3.5A,I	7.5-8.0A
No Symptoms - ETT++	5.0-7.0A,I	2.0-2.5A,I	6.5-7.0I
No Symptoms - ETT±	2.6-5.0I,A	1.5-2.0I	4.0-6.0DI

Notes:

1. CABG scores are 2-3 points lower in the very high comorbidity risk group. Where a range is shown, scores are lower if the EF <25%.

TABLE 7

ASYMPTOMATIC PATIENT WITH CORONARY ARTERY DISEASE

	<u>CABG VS. MEDICAL RX</u>	<u>CABG VS. PTCA</u>	<u>PTCA VS. MEDICAL RX</u>
<u>Left Main Disease</u>			
ETT++	9.0A	9.0A	4.0I
ETT±	9.0A	9.0A	2.0I
<u>Three Vessel Disease</u>			
ETT++	8.5-9.0A	7.5I	8.0A
ETT±	5.5-6.0A	5.0-5.5A, I	5.0-5.5A
<u>Two Vessel Disease</u>			
<u>With LAD Involvement</u>			
ETT++	8.0A	7.0D	8.0A
ETT±	4.5-6.0I	3.5-5.0I	5.0I
<u>Two Vessel Disease</u>			
<u>Without LAD Involvement</u>			
ETT++	7.0A, I	4.0-4.5A	7.5A
ETT±	3.5I	2.0I	4.5I
<u>Single Vessel Disease</u>			
<u>Without LAD Involvement</u>			
ETT++	7.5-8.0A, I	4.0-4.5I	8.0A
ETT±	3.0-4.0D	2.0-2.5I	4.0D
<u>Single Vessel Disease</u>			
<u>Without LAD Involvement</u>			
ETT++	5.0-5.5D	3.0I	7.0I
ETT±	2.5I	2.0A	3.0I

Notes:

1. Ejection fraction split for all ratings was at $> 50\%$ or $\leq 50\%$. Where a range is shown the lower score is for EF $> 50\%$.
2. CABG scores are 1-2 points lower and PTCA scores are minimally lower in the very high comorbidity risk group.

TABLE 8

PATIENT WITH SEVERE COMORBIDITIES THAT WOULD PRECLUDE CABG EVEN IF PTCA FAILED. RATINGS ARE FOR PTCA COMPARED TO MEDICAL THERAPY

	<u>1MD</u>	<u>3VD</u>	<u>2VD</u>	<u>1VD</u>
Severe Chronic Stable Angina on Maximal Medical Therapy	5.0A	7.5I	7.0I	8.0I
Unstable Angina on Maximal Medical Therapy	5.0A	8.5I	8.5I	8.5I
Acute Myocardial Infarction				
Cardiogenic Shock	5.0D	7.0I	7.5I	7.5I
Continuing Pain on Maximal Medical R	5.0A	7.5I	7.5I	8.0I
Post Myocardial Infarction With Continuing Pain on Maximal Medical R	5.0A	8.0I	8.5I	9.0I

TABLE 9

OTHER CLINICAL SUBGROUPS

	<u>CABG VS. MEDICAL RX</u>	<u>CABG VS. PTCA</u>	<u>PTCA VS. MEDICAL RX</u>
Near Sudden Death Without AMI (any anatomy, ejection fraction or level of ischemia)	9.0A	7.0A	9.0A
CABG With Valve Surgery	9.0A	---	---

The following comments apply to all tables:

- (1) Results are shown for patients with normal or low risk from comorbidities. The effects of higher comorbidity risk levels are greater for CABG than for PTCA and are greater for three, two, or single vessel disease than left main disease. See footnotes to tables for specific effects.
- (2) Where ejection fraction affects ratings, a range of scores is provided. The lower score generally corresponds to an ejection fraction of <25%. For Chronic Stable Angina the lower score applies to both ejection fractions of <25% and >50%.
- (3) The letters A, I, and D following the median scores indicate the degree of agreement among panelists (A = agreement, D = disagreement, and I = intermediate). Where two letters appear, the first listed refers to two of the three levels of EF, usually <25% and >50%, and the second letter to EF <25-50%.

CHRONIC STABLE ANGINA (TABLE 3)

Left Main Disease (LMD):

- CABG is highly appropriate and unequivocally preferred over medical treatment or PTCA regardless of the severity of angina, use of maximal medical therapy, and even in the presence of very high risk from comorbidities.
- Very high risk reduces CABG scores by only one point (from 9 to 8). Use of PTCA is inappropriate, or at best highly equivocal, in LMD.

Three Vessel Disease (3 VD):

- CABG is strongly preferred over continued medical therapy regardless of the severity of angina and regardless of whether the patient is receiving maximal medical therapy.
- PTCA is also preferred over medical therapy but only marginally so in the patient with mild angina who is receiving submaximal medical therapy.
- CABG is preferred over PTCA in 3 VD unless the EF is <25% or the risk from comorbidities is high or very high. Under these circumstances, the choice between CABG and PTCA is equivocal.

Two Vessel Disease with LAD Involvement (2 VD with LAD):

- Ratings are much more sensitive to symptom severity, ejection fraction, comorbidity risk level, and whether the patient is receiving maximal medical therapy than for LMD or 3 VD.
- CABG is preferred over medical therapy unless the patient has very high risk from comorbidities. Both CABG and PTCA are preferred over medical therapy unless the patient has

two or more of the following characteristics (mild symptoms, negative ETT, submaximal medical therapy, EF <25% or >50%). CABG is preferred over PTCA if the patient has two of the following characteristics (EF 25 - 50%, ETT strongly positive, maximal medical therapy); otherwise the choice of procedure type is equivocal. Considerable disagreement was expressed over the choice between CABG and PTCA when the patient is on submaximal therapy.

Two Vessel Disease without LAD Involvement (2 VD without LAD):

- Ratings are about a point lower for both CABG and PTCA than in patients with 2 VD with LAD.
- Use of either procedure is equivocal if the ETT is negative and angina is mild.
- PTCA is preferred over CABG if the comorbidity risk is very high or high. Otherwise, the choice of procedure type is equivocal.

Single Vessel Disease with LAD Involvement (1 VD with LAD):

- Results are similar to 2 VD without LAD.
- PTCA is preferred over CABG if symptoms are mild and EF is 25% - 50%.
- If angina is severe, the choice of procedure type is equivocal.

Single Vessel Disease without LAD Involvement (1 VD without LAD):

- PTCA is uniformly preferred over CABG.
- Use of PTCA is equivocal if symptoms are mild and the ETT is negative.
- CABG is inappropriate if symptoms are mild and ETT is negative, or if comorbidity risk is high or very high.
- Considerable disagreement was expressed over the effect of EF on the choice of either procedure compared to medical therapy.

UNSTABLE ANGINA (TABLE 4)

Left Main Disease (LMD):

- Results are very similar to chronic stable angina.
- CABG is highly appropriate and preferred over PTCA.
- Considerable disagreement was expressed over the use of PTCA in LMD.

Three Vessel Disease (3 VD):

- Results are very similar to chronic stable angina.
- CABG is preferred over PTCA unless the comorbidity risk is very high.

Two Vessel with LAD Involvement (2 VD with LAD):

- CABG and PTCA are both highly appropriate compared to medical therapy whether or not symptoms persist or the ETT is positive.
- PTCA is preferred over CABG if the comorbidity risk is a very high group; otherwise the choice between CABG and PTCA is equivocal.

Two Vessel Disease without LAD Involvement (1 VD without LAD):

- Similar to 2 VD with LAD except that use of either procedure is equivocal if symptoms are absent and the ETT is negative.
- PTCA is preferred over CABG if the patient's comorbidity risk group is high or very high.

Single Vessel Disease with LAD Involvement (1 VD with LAD):

- Similar to 2 VD without LAD.

Single Vessel Disease without LAD Involvement (1 VD without LAD):

- PTCA is appropriate and preferred over CABG unless symptoms are absent and the ETT is negative; in this case, use of PTCA is equivocal.

ACUTE MYOCARDIAL INFARCTION (FIRST SIX HOURS) (TABLE 5)

Cardiogenic Shock

Left Main Disease:

- Both CABG and PTCA are appropriate, but CABG is the preferred treatment unless the patient has very high comorbidity risk. In this case, choice of therapy is equivocal.

Three Vessel Disease:

- Both CABG and PTCA are appropriate and the choice between them is equivocal.
- If the patient has very high comorbidity risk, PTCA is preferred.

Two Vessel Disease:

- Both CABG and PTCA are appropriate and the choice is equivocal unless the patient has high or very high comorbidity risk. In this case PTCA is preferred.

Single Vessel Disease:

- Both CABG and PTCA are appropriate, but PTCA is preferred regardless of comorbidity risk group.

Evolving AMI without Pain

Regardless of anatomy, use of CABG is inappropriate, and use of PTCA is equivocal. Considerable disagreement was evident among panelists on this conclusion, however.

Evolving AMI with Continuing Pain

Left Main Disease:

- CABG is appropriate regardless of prior use of thrombolytic agents, and use of PTCA is equivocal.
- CABG is preferred over PTCA unless the patient has very high comorbidity risk. In this case, use of either procedure is equivocal.

Three Vessel Disease:

- CABG and PTCA are both appropriate compared to medical therapy.
- Prior use of thrombolytic agents decreases the CABG score by about one point but does not affect the PTCA score.
- Choice between CABG and PTCA is equivocal and subject to disagreement among panelists.
- PTCA is preferred in the very high comorbidity risk group.

Two Vessel Disease with LAD Involvement:

- Results similar to 3 VD.

Two Vessel Disease without LAD Involvement:

- PTCA is appropriate and CABG is equivocal compared to medical therapy.
- PTCA is strongly preferred over CABG in all risk groups.

Single Vessel Disease with LAD Involvement:

- PTCA and CABG are both appropriate compared to medical therapy.
- Prior use of thrombolytic agents decreases scores for CABG by about one point.
- PTCA is strongly preferred over CABG in all risk groups and especially if EF <25%.

Single Vessel Disease with LAD Involvement:

- PTCA is appropriate and CABG is equivocal compared to medical therapy.
- PTCA is strongly preferred over CABG.

POST MYOCARDIAL INFARCTION (WITHIN 21 DAYS) (TABLE 6)

Left Main Disease:

- CABG is highly appropriate compared both to medical therapy and PTCA if the patient has continuing pain or is asymptomatic but has a strongly positive ETT.
- CABG is still appropriate, though less strongly so, if the patient is asymptomatic with a negative or weakly positive ETT.
- Use of CABG is equivocal if the patient has a very high comorbidity risk and an EF <25%.

Three Vessel Disease:

- CABG and PTCA are both appropriate compared to medical therapy if the patient has continuing pain or a strongly positive ETT.
- CABG is preferred over PTCA in such patients unless the EF is <25% or the comorbidity risk is very high. In these cases, the choice of procedure is equivocal.
- The use of either procedure is equivocal if the patient is asymptomatic and has a negative or weakly positive ETT, especially if the EF is <25% or the comorbidity risk is very high.

Two Vessel Disease with LAD Involvement:

- Results are very similar to 3 VD.

Two Vessel Disease without LAD Involvement:

- Results are similar to 3 VD except that all scores are about one point lower.
- CABG is inappropriate and PTCA is preferred if the EF <25% or the patient has high or very high comorbidity risk.

Single Vessel Disease with LAD Involvement:

- Similar to 2 VD without LAD, except that CABG is inappropriate in the asymptomatic patient with a negative or weakly positive ETT in all comorbidity risk groups.
- Considerable disagreement was expressed over the choice between CABG and PTCA.

Single Vessel Disease without LAD Involvement:

- CABG and PTCA are both appropriate compared to medical therapy in the patient with continuing pain or a strongly positive ETT as long as the comorbidity risk is low or normal and the EF is >25%. CABG is inappropriate if the EF <25% or the comorbidity risk group is high or very high.
- PTCA is strongly preferred over CABG, however.
- Use of either procedure is equivocal in the asymptomatic patient with a negative ETT.

ASYMPTOMATIC PATIENT WITH CORONARY ARTERY DISEASE (TABLE 7)

Left Main Disease:

- CABG is highly appropriate regardless of ETT results and strongly preferred over PTCA.
- PTCA use is equivocal when the ETT is strongly positive and inappropriate if the ETT is negative or weakly positive.

Three Vessel Disease:

- If the ETT is strongly positive, both CABG and PTCA are appropriate, but CABG is preferred.
- The choice between CABG and PTCA is equivocal if the patient is at very high risk from comorbidities.
- If the ETT is negative or weakly positive, use of either procedure is equivocal.

Two Vessel Disease with LAD Involvement:

- If the ETT is strongly positive, conclusions are similar to those for 3 VD.
- If the ETT is negative or weakly positive, use of either procedure is equivocal and CABG is inappropriate if the EF is >50% or the comorbidity risk is very high.

Two Vessel Disease without LAD Involvement:

- If the ETT is strongly positive, both CABG and PTCA are appropriate, and the choice between them is equivocal.
- If the comorbidity risk is very high, PTCA is preferred.
- If the ETT is negative or weakly positive, use of CABG is inappropriate and PTCA is highly equivocal.

Single Vessel Disease with LAD Involvement:

- Similar to 2 VD without LAD.

Single Vessel Disease without LAD Involvement:

- If the ETT is strongly positive, use of PTCA is appropriate, CABG is equivocal, and PTCA is strongly preferred.
- If the ETT is negative or weakly positive, neither procedure is appropriate.

PATIENT WITH SEVERE COMORBIDITIES THAT WOULD PRECLUDE CABG IF THE PTCA FAILED (TABLE 8)

- PTCA would be appropriate in one, two, or three vessel disease and equivocal in LMD, regardless of whether the patient had severe chronic stable angina, unstable angina, AMI, or was post MI with continuing pain.

OTHER CLINICAL SUBGROUPS (TABLE 9)

Near Sudden Death with Any Anatomy, EF or Level of Ischemia:

- CABG is highly appropriate and preferred over PTCA.

CABG with Valve Surgery:

- CABG is highly appropriate compared to medical therapy.

4.0 CALCULATION OF APPROPRIATENESS SCORES FOR CARDIAC SURGERY PROGRAMS

Appropriateness ratings could be used in several different ways to judge the overall appropriateness of CABG and PTCA procedures performed by in the Medicare Heart Bypass Demonstration Centers. Alternatives include:

- (1) calculation of the percent of all CABGs that were performed for appropriate, equivocal, or inappropriate indications;
- (2) calculation of a Continuous Appropriateness Score that uses the actual rating (1 to 9) for each indication as the weight; and
- (3) calculation of a Weighted Appropriateness Score that uses modified weights for each indication based on the level of appropriateness.

4.1 Percent Appropriate

This calculation would use the scoring algorithm developed by RAND which defines appropriate, inappropriate, and equivocal indications as follows:

Appropriate - median rating of 7 to 9 with either "A" or "I" levels of agreement.

Equivocal - median rating of 4 to 6 with "A" or "I" levels of agreement or a median rating of 1 to 3 or 7 - 9 in the presence of disagreement. Indications with uncertainty sufficient to cause disagreement among panelists logically are of equivocally appropriate.

Inappropriate - median rating 1 to 3 with either "A" or "I" levels of agreement.

Advantages of this scoring system would be relative simplicity and the ability to compare results in Medicare Heart Bypass Demonstration Centers to hospitals being examined currently by RAND and the Consortium of Academic

Medical Centers. Disadvantages are that such a system does not make full use of the interval properties of the rating scale. For example, an appropriateness rating of 7 is clearly different than a rating of 8 or 9 and a rating of 4 is different from 6.

4.2 Continuous Appropriateness Score

This calculation would use the actual score assigned to each patient-specific indication. Advantages are that such a score would take maximal advantage of the ratings to create a score that reflects expected total net benefits to the patients treated by a cardiac surgery program based on patient selection criteria. Since a rating is defined as a measure of the extent to which the benefits exceed the risks for a given comparison of two treatments (e.g., CABG versus medical therapy), the sum would be an estimate of the program's net benefits. One disadvantage is that the rating scale is not truly continuous, and intervals between two points on the scale may not be exactly equal. Moreover, intervals between points in the equivocal range may be less reliable both because they reflect narrower differences in net benefits and greater degrees of uncertainty.

4.3 Weighted Appropriateness Score

This calculation would be a compromise between the other two approaches. It would retain the degree of discrimination reflected at the appropriate and inappropriate ends of the rating scale, while aggregating those in the equivocal range. Weights assigned might be as follows:

<u>Weight</u>	<u>Rating</u>
+ 3	9
+ 2	8
+ 1	7
<u>0</u>	<u>4-6</u>
- 1	3
- 2	2
- 3	1

4.4 Pretest of Appropriateness Model

Our plan will be to pre-test all three scoring methodologies during baseline assessments of indications for CABGs and PTCAs performed in the Medicare Heart Bypass Demonstration Centers during 1990. Objectives of the pre-test will be:

- (1) to determine the extent to which data required to classify patients by indications are available from the cardiac surgery and cardiac catheterization registries;
- (2) to determine the accuracy of these data by comparing them with medical record abstractions; and
- (3) to compare conclusions on the appropriateness of CABG and PTCA in the Centers by the three scoring methods.

Pre-test Design

The analysis baseline assessment of indications for CABG and PTCA will include 100 patients receiving each type of procedures in each Medicare Heart Bypass Demonstration Center between January 1, 1990 and December 31, 1990. Patients will be randomly selected from complete patient rosters. Data describing the clinical characteristics of these patients will be obtained from three sources: (1) medical records; (2) cardiac catheterization registry; and (3) cardiac surgery registry. Medical record data will serve as the "gold standard" against which the reliability of registry data will be compared.

Data Elements:

Treatment Variables:

- type of procedure (CABG, PTCA, both);
- characteristics of procedures (number and types of bypasses or dilations);
- concurrent valve surgery; and
- other procedures

Patient Characteristics:

- clinical subgroup of patient;

- location and extent of coronary artery disease including percent stenosis of each diseased vessel
- suitability of vascular lesions for PTCA;
- procedure status: elective, urgent, emergent;
- left ventricular ejection fraction;
- severity of angina;
- pre-procedure treatment for angina;
- use of thrombolytic agents (in patients with AMI);
- presence of preoperative cardiogenic shock;
- pre-operative use of IABP;
- exercise tolerance results; and
- comorbidities: age, sex, obesity, reoperation, diabetes, hypertension, dialysis dependency, COPD on medications, peripheral vascular disease, symptomatic carotid artery disease

Data collection from medical records and relevant cardiac registries will be guided by an explicit protocol and performed by trained abstractors. Ten percent of records will be reabstracted independently by a second abstractor to examine the reliability of the abstraction process.

The analysis will focus first on comparing information obtained from the three sources. Missing data, conflicting results for individual variables, and their effects on the appropriateness score all will be of interest. Appropriateness scores will then be calculated for CABG and PTCA using the three methodologies described previously.

- Chassin MR, Park RE, Fink A, Rauchman S, Keesey J, Brook RH. Indications for Selected Medical and Surgical Procedures: A Literature Review and Ratings of Appropriateness. RAND Corporation, Santa Monica, CA. May 1986.
- Leape LL. Practice Guidelines and Standards: An Overview. Quality Review Bulletin 1990; 16:41-49.
- Parsonnet V, Dean D and Bernstein E. A Method of Uniform Stratification of Risk for Evaluating the Results of Surgery in Acquired Heart Disease. Circulation, 1989; 79(Suppl.I):I-3 - I-12.

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